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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,914	05/30/2001	Neil Andrew Williams	5440US.cip	8062

7590

03/31/2005

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EXAMINER

BORIN, MICHAEL L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/867,914

Applicant(s)

WILLIAMS ET AL.

Examiner

Michael Borin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 69-87 is/are pending in the application.
- 4a) Of the above claim(s) 70,73,80 and 82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 69,71,72,74-79, 81,83-87 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

*lil*

## **DETAILED ACTION**

### **CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/04/2004 has been entered.

### ***Status of Claims***

2. Amendment and response filed 11/04/2004 is acknowledged. All Previous claims are canceled. Claims 69-87 are added. Applicant has previously made election of species, EtxB as agent, and insulin as antigen. Consequently, claims 70,73,80,82 are withdrawn from consideration as drawn to non-elected species. Claims 69,71,72,74-79, 81,83-87 are examined to the extent they read on the elected species.

### ***Priority***

3. As discussed previously, this application is continuation-in-part of application 09/999458. As the parent application did not address compositions comprising insulin, the claims of instant application drawn to such compositions do not have benefit of earlier filing date of prior application(s) and have priority date of this application, 05/30/2001. In the response filed 11/04/2004 applicant argues that since the

specification of the parent application mentions diabetes, it supports use of insulin as an antigen. Examiner disagrees. Disclosure in an application that merely renders the later claimed invention obvious is not sufficient to meet the written description requirement of 35 USC 112, first paragraph. In *Purdue Pharma L.P. v. Faulding Inc.*, 230, F.3d 1320, 1326, 56, USPQ2d 1481, 1486 (Fed. Cir. 2000), the court noted that with respect to *In re Ruschig* (379 F.2d 990, 154, USPQ 118 (CCPA 1967)) that "Ruschig makes clear that one cannot disclose a forest in the original application and then later pick up a tree out of the forest and say 'here is my invention'. In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in originally filed disclosure."

Examiner maintains that as the parent application did not address compositions comprising insulin, the claims of instant application drawn to such compositions do not have benefit of earlier filing date of prior application(s) and have priority date of this application, 05/30/2001.

Consequently, the following rejection of record is maintained.

**Claim Rejections - 35 U.S.C. § 102 and 103.**

4. Claims 69, 71, 72, 74-79, 81, 83-87 are rejected under 35 U.S.C. 102(b) as anticipated by Uda et al. (US 554378).

The instant claims are drawn to pharmaceutical composition comprising EtxB and insulin.

Uda teaches composition comprising B subunit of Etx and insulin. See claims 1,7,14.

In regard to intended use recited in the claims, arguments related to the intended use of the composition are of little relevance in determining the patentability of the composition. *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974). Suggested use limitations do not impart patentability to composition claims where the composition is otherwise anticipated by the prior art.

Specifically, in regard to claims 72,79, B subunit of Etx and insulin are not linked together.

Specifically, in regard to claims 75,84, the composition can be in the form of aqueous solution, or an ointment (i.e., lotion) – col. 5-6.

Specifically, in regard to claims 76,85, the composition can have preservatives (col. 5-6).

Specifically, in regard to claims 77,78,86,87, the aqueous formulation is considered as being to be “adapted” for systemic, oral, mucosal, etc, administration.

#### Response to arguments

Applicant argues that because this application should be entitled to earliest filing date of July 5, 1995 of the foreign priority application, the Udo reference can not be applied as a prior art. The benefit of earlier filing date of prior application has not been granted for the reasons discussed above.

The rejection is maintained.

***Conclusion.***

5. No claims are allowed

6. This is an RCE of applicant's application No. 09/867914. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Borin, Ph.D.

Primary Examiner

Art Unit 1631

A handwritten signature in black ink, appearing to read 'Michael Borin', is written over the printed name and title.

3/25/05